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(29)

To: _____

see form PCT/ISA/220

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/IL2005/000304

International filing date (day/month/year)
17.03.2005

Priority date (day/month/year)
18.03.2004

International Patent Classification (IPC) or both national classification and IPC
A61F2/00

Applicant
CONTIPI LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 24-27

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 24-27

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See separate sheet for further details

**WRITTEN OPINION OF THE
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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☒ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-23, 28-30

Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	6,7,12
	No: Claims	1-5,8-11,13,14-20,21-23, 28-30
Inventive step (IS)	Yes: Claims	
	No: Claims	1-23,28-30
Industrial applicability (IA)	Yes: Claims	1-23, 28-30
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III.

Rule 39.1(iv) and Rule 67.1 (iv) PCT - Method for treatment of the human or animal body by therapy: Claims 24-27 disclose a method of using an apparatus for the treatment of urinary incontinence.

Re Item IV.

The separate inventions/groups of inventions are:

- Claims 1-23: an apparatus for treating urinary incontinence.
- Claims 28-30: an apparatus for inserting a vaginal device

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons: the document US5785640 cited in our search report discloses an apparatus for treating urinary incontinence. Beyond this prior art, the special technical features (in the meaning of Rule 13.2 of the P.C.T) left in the independant claims 1, 14, 21, 28 of the application are:

- In independant claims 1, 14, 21 : none.
- In independant claim 28: an apparatus for inserting a vaginal device.

No same or correspondent special technical feature can be found between claims 1, 14, 21 and claim 28. There is therefore no technical relationship involving same or corresponding special technical features between claims 1, 14, 21 and claim 28.

The inventions defined in the above-mentioned claims are not linked by a common inventive concept.

Re Item V.

1 Reference is made to the following documents:

- D1 : US 5 785 640 A (KRESCH ET AL) 28 July 1998 (1998-07-28)
- D2 : US 5 483 976 A (MCLAUGHLIN ET AL) 16 January 1996 (1996-01-16)
- D3 : US 6 418 930 B1 (FOWLER ROBERT STUART) 16 July 2002 (2002-07-16)
- D4 : EP 0 264 258 A (ZEDLANI PTY. LIMITED) 20 April 1988 (1988-04-20)

D5: US-B1-6 645 136 (ZUNKER MARYANN ET AL) 11 November 2003 (2003-11-11)

2 INDEPENDENT CLAIM 1

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (the references in parentheses applying to this document) (see column 4, line 40 to column 8, line 59): an apparatus (4) for treating urinary incontinence, comprising: a node; a support section (6, 8) adapted for providing urethral support attached to said node; and an anchoring section (10, 12) adapted for resisting movement of said apparatus attached to said node; wherein said node is no longer than 30% of the entire length of said apparatus comprising said node, support section and said anchoring section together.

This disclosure corresponds to the subject-matter of claim 1.

Documents D3 and D4 disclose as well the subject-matter of claim 1.

The subject matter of claim 1 is therefore not new in the sense of Art.33(2) PCT.

3 INDEPENDENT CLAIM 14

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 14 is not new in the sense of Article 33(2) PCT.

Document D2 discloses (the references in parentheses applying to this document): an apparatus (10) for treating urinary incontinence, comprising a support (4) section adapted for providing urethral support; and an extending insert (12) adapted to adjust the diameter of said support section.

This disclosure corresponds to the subject-matter of claim 14.

4 INDEPENDENT CLAIM 21

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 21 is not new in the sense of Article 33(2) PCT.

Document D1 discloses (the references in parentheses applying to this document): an apparatus for treating urinary incontinence, comprising: a body (4) adapted for treating incontinence when inserted in a vagina; and a device displacer (128) for providing movement to said apparatus.

This disclosure corresponds to the subject-matter of claim 21.

5 INDEPENDENT CLAIM 28

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 28 is not new in the sense of Article 33(2) PCT.

Document D5 discloses (the references in parentheses applying to this document): an apparatus (100) for inserting a vaginal device comprising an enclosure (110) for containing said vaginal device and a stopper, wherein said stopper prevents over insertion.

This disclosure corresponds to the subject-matter of claim 28.

6 DEPENDENT CLAIMS 2-5, 8-11, 13, 15-20, 22, 23, 29-30

Dependent claims 2-5, 8-11, 13, 15-20, 22, 23, 29-30 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

6 DEPENDENT CLAIMS 6, 7, 12

The additional features of claims 6, 7, 12 represent standard features in the field and are considered to be obvious. The features of these claims merely refer to the application of known equipment (a cover or interlinking support struts).

Re Item VIII.

- 7 Although claims 1, 14 and 21 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.

**WRITTEN OPINION OF THE
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AUTHORITY (SEPARATE SHEET)**

International application No.

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- 8 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
- 9 Claim 29 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.